IN THE UNITED STATES DISCTRICT COURT
FOR THE SOUTHERN DISTRCIT OF WEST VIRGINIA
CHARLESTON DIVISION

In RE: BOSTON SCIENTIFIC CORPORATION
PELVIC REPAIR SYSTEMS PRODUCTS
LIABILITY LITIGATION MDL No.: 2326

THIS DOCUMENT RELATES TO:

Kimberly Allen v. Boston Scientific Corporation, 2:17-cv-01837
Perla Alvarado v. Boston Scientific Corporation, 2:17-cv-02243
Christine Babcock v. Boston Scientific Corporation, 2:17-cv-00701
Charise Beach v. Boston Scientific Corporation, 2:17-cv-2112
Michelle Briggs v. Boston Scientific Corporation, 2:17-cv-01844
Tracy Brown v. Boston Scientific Corporation, 2:17-cv-01243
Amy Busby v. Boston Scientific Corporation, 2:17-cv-2111
Sandra Clark v. Boston Scientific Corporation, 2:17-cv-02110
Jaime Conley v. Boston Scientific Corporation, 2:17-cv-01940
Linda Dembski v. Boston Scientific Corporation, 2:17-cv-01074
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Tracy Lowrie v. Boston Scientific Corporation, 2:17-cv-01959
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Mary Masterson v. Boston Scientific Corporation, 2:17-cv-02417
Rhea Notestinev v. Boston Scientific Corporation, 2:17-cv-00534
Donna Palmer v. Boston Scientific Corporation, 2:17-cv-02416
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Armentha Price v. Boston Scientific Corporation, 2:17-cv-01939
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Andra Shaw v. Boston Scientific Corporation, 2:17-cv-02745
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PLAINTIFFS' MOTION AND MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF STEVEN R. LITTLE, Ph.D.

Pursuant to Federal Rules of Evidence 702, 403 and 104, Plaintiffs submit this Motion and Memorandum of Law in Support of their Motion to Exclude the Opinions and Testimony of Steven R. Little, PhD.

Introduction and Summary

Dr. Steven R. Little is a chemical engineer who has experience in the field of biomaterials including polypropylene. Unfortunately, Dr. Little attempts to opine on subjects that are outside his expertise and for which he has conducted no testing or studies, or engaged in meaningful differential analysis of competing theories, rendering his opinions unreliable and unsupported. Specifically, Dr. Little attempts to offer inappropriate opinions related to oxidative degradation of polypropylene mesh without a requisite foundation including having never personally examined the mesh at issue in any capacity. Dr. Little further attempts to improperly offer opinions as to the state of mind of non-party Chevron Phillips' Material Safety Data Sheet (MSDS) with no expertise or substantive knowledge. Because each of these opinions lacks the required reliability of Rule 702, these opinions should be excluded by the Court.

Arguments and Authorities

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has

been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence form which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: [E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony… is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry*, 178 F.3d at 261 and *Daubert*, 509 U.S. at 588, 595.) This Court "need not determine that the proffered expert testimony is irrefutable or certainly correct" – [a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Maryland Cas. Co.*, 137 F.3d at 783 (noting that [a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable and helpful").

Daubert mentioned specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States*

v. Crisp, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."') (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert's* five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.... Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (internal citations and quotation marks omitted). Even if the expert is qualified and the testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must "fit" the case, *i.e.* there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

A. **Dr. Little should be precluded from offering *any* opinions related to oxidative degradation.**

Dr. Little should be precluded from offering any opinions related to *in vivo* mesh degradation in these cases. In his expert report, Dr. Little states that "[p]olypropylene is considered a biostable, hydrophobic, and non-degradable biomaterial" and that "the conditions in the human body would not lead to material degradation of the polypropylene mesh." Report of Stephen F. Little, PhD, dated May 27, 2017 attached at Ex. 1 at 6. Dr. Little relies extensively on a single 1976 study and an untested hypothesis that biological material adherent to the mesh effectively gives the illusion of degradation when not properly cleansed. This fails to establish a reliable foundation under *Daubert*.

With regard to the impact of the human body on polypropylene mesh, Dr. Little concedes that he is not a physician, pathologist or histopathologist Ex. 2, Deposition of Stephen F. Little, PhD, 13:16-14:6. He has never personally analyzed or tested any mesh device. *Id*. at 14:13-19:20. While Dr. Little opines on the benefit of FTIR analysis for determining degradation, he has never performed this test – or any other -- on any explanted mesh or other polypropylene product. *Id.* at 16:24-17:2. While Dr. Little possessed the opportunity to conduct this analysis and other testing discussed in his expert report, he instead implausibly testified that there were no explanted meshes available in the mesh litigations. *Id*. at 17:3-20. Dr. Little cannot support his opinions on degradation because he failed to investigate the evidence in support of the degradation that was readily available to him and instead relied upon his untested alternative hypotheses.

Even more concerning, Dr. Little failed to meaningfully consider the extensive body of literature in which degradation was identified by other researchers' testing and studies. When confronted with the contrary conclusions of Dr. Celine Mary, in which polypropylene material

was actually examined and found to be degraded *in vivo*, Dr. Little resorted to mere repeated speculation that the author's conclusions were faulty because biological material may have remained. *Id*. at 132:19-136:9 (reviewing Ex 4, Mary, et al., Comparison of the in vivo behavior of polyvinylidene fluoride and polypropylene sutures used in vascular surgery. ASAIO J. 1998 May-Jun;44(3):199-206). Dr. Little conceded that the evidence of stress cracking "looks exactly like the "biological material" of his hypothesis, yet relied on the mere photographs within the study to disregard Dr. Mary's contrary conclusions. *Id*. at 135:2-136:9. As Dr. Little testified that the visual photographic evidence for degradation and his alternative theory would be exactly the same in his opinion, he lacked any principled basis for disregarding Dr. Mary's conclusions of *in vivo* degradation. Dr. Little's contrary opinion, lacking testing, peer review or any standard other than his own visual acuity, lacks the reliability required by *Daubert*.

Dr. Little further disregarded referenced sources within Dr. Mary's research on the basis that these secondary authors failed to personally conduct any studies, rendering their opinions mere speculation. *Id*. at 139:11-140:16. However, this is exactly the basis for Dr. Little's own opinion: mere speculation without conducting any study. "Testing, in particular, is often a key component of the *Daubert* inquiry, and the failure to properly test a hypothesis is often grounds for excluding expert testimony in this jurisdiction. *See, e.g., Marsh v. W.R. Grace & *555 Co.*, 80 Fed.Appx. 882 (4th Cir. 2003); *Tunnell v. Ford Motor*, 245 Fed.Appx, 283, 287 (4th Cir. 2007). Also, of critical importance to the *Daubert* inquiry is that the expert rule out alternative hypotheses. *See Higginbotham v. KCS Intern.*, 85 Fed.Appx, 911, 916 (2004)." *Fireman's Fund Ins. Co., v. Tecumseh Products Co.*, 767 F. Supp. 2d 549, 554-55 (D. Md. 2011). In this case, Dr. Little not only failed to test, but excluded Dr. Mary's contrary conclusion based on

photographic evidence that would appear "exactly" the same to his eyes. This fails to meet the reliable methodology requirements of *Daubert*.

Similarly, Dr. Little dismisses the contrary findings of Dr. Clave, that polypropylene is not inert and does degrade *in vivo*. Ex. 2, 205:21-210:23 (reviewing Ex. 5, Clave, A et al. polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J (2010) 21:261–270). Dr. Little admits that Dr. Clave's research concluded that polypropylene is not inert *in vivo*, subsequently reaches a contrary and ultimately rejected conclusion without offering foundation for this rejection, and then concedes that both biological material *and* degradation could be occurring. *Id*. at 210:9-210:23. Accordingly, Dr. Little's opinion remains based on untested speculation, a disregard of testing and the direct observation by those conducting the studies, fails to offer a principled basis for ruling out these alternative hypotheses and ultimately does not exclude that degradation was occurring. It is accordingly unreliable and of no use to the jury.

Dr. Little failed to find evidence of degradation because he did not look for it. He disregarded contrary conclusions based on photographs that cannot distinguish between biological material and degradation, or mere speculation, and undermined his ultimate conclusion that degradation cannot occur by conceding that both processes may be occurring. Dr. Little should be precluded under Rule 702 from offering testimony related to degradation, based on his untested theory and because of his willful blindness towards all contrary evidence.

A. Dr. Little's State of Mind or Intent Opinions Related To Material Safety Data Sheets (MDSD) Should Be Struck.

Under Rule 702, expert testimony is inadmissible unless the expert's opinions are "the product of reliable principles and methods." FED. R. EVID. 702. An expert opinion must be grounded in the "methods and procedures of science," and must consist of more than "subjective

believe or unsupported speculation." *Daubert*, 509 U.S. at 589. Dr. Little's inexpert thoughts on why Chevron Phillips included certain language in its MSDS is neither based on reliable methodology not grounded in anything other than unsupported speculation. It should accordingly be excluded.

At issue are the MSDS created by Chevron Phillips, the manufacturer of the Marlex polypropylene used in Boston Scientific mesh products, including the Obtryx product. Chevron Phillips added the following statement in the Marlex MSDS:

> MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Ex. 3 at p. 1. Lacking any personal knowledge or identifying any review of relevant documents, Dr. Little opines "The Medical Application Caution on the first page of the MSDS is consistent, in my experience, with statements made by many raw material suppliers who seek to avoid liability for the use of their product in medical products."

Dr. Little offers no evidence in his report, deposition, or resume that he has any experience creating, reviewing, or analyzing MSDS. *See* Ex. 1; Ex. 2 at 192:5-197:8. Therefore, he is likewise unqualified to offer opinions related to MSDS. Moreover, Dr. Little offers nothing more than mere speculation that the caution against *in vivo* use is for liability evasion purposes. *Id*. Such a speculative, unqualified and ultimately legal conclusion is a lay opinion of no help to the trier of fact. As Dr. Little fails to offer any qualification or substantive basis for rendering an opinion as to Chevron Phillips' state of mind, *Daubert* precludes him from offering testimony on that entity's MSDS or the reasons underlying the language it chose to include.

Finally, this Court previously excluded the exact same kind of testimony that Boston Scientific now seeks to offer into evidence through Dr. Little. *Tyree v. Boston Sc. Corp.*, No.

2:12-cv-08633, 2014 U.S. Dist. LEXIS 155138 at *47 (S.D. W. Va., Oct 29, 2014). Dr. Little's opinion is merely the latest backdoor attempt to offer opinions about Chevron Phillips' state of mind or intent which has routinely been excluded by this Court. *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied.* 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013). These same opinions should be excluded here.

CONCLUSION

For the foregoing reasons, Dr. Little's proposed testimony and opinions outlined above are inadmissible and should be excluded.

DATED: January 11, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2018, a true and correct copy of this Response and exhibits was served via electronic mail with the Clerk of the Court using the CM/ECF System, which will send notification of such filing to the CM/ECF counsel of record.

Brian A. Goldstein, Esq.